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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DEBORAH L. DIHEL and GHISLAINE JOLY

Appeal 2009-007497
Application 10/783,078
Technology Center 1600

Decided: November 16, 2009

Before DONALD E. ADAMS, LORA M. GREEN, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a dissolvable film and methods for making the film. The Patent Examiner rejected the claims as being obvious. We have jurisdiction under 35 U.S.C. § 6(b) (2002). We reverse.

STATEMENT OF THE CASE

The invention concerns dissolvable film comprising an active ingredient and a method of manufacture. (Spec. Title.) The Specification states that the invention “provides a film that can be used to deliver a substance, such as a flavor or a therapeutically active ingredient, and is particularly useful when the substance to be delivered is a volatile substance.” (*Id.* at 3.)

Claims 1-13, which are all the pending claims, are on appeal. Claims 1 and 6 are representative and read as follows:

1. A method of making a dissolvable film comprising a substance, the method comprising mixing film forming ingredients together to form a mixture, coating the mixture onto a suitable substrate to form a film, applying a substance to the film, and drying the film to a moisture content of about 10 weight % or less moisture.
6. A dissolvable film having disposed on at least one surface thereof an encapsulated substance.

The Examiner rejected claims 1-13 under 35 U.S.C. § 103(a) as unpatentable over Leung.¹

OBVIOUSNESS

The Issue

The Examiner found that Leung described dissolvable films comprising water-soluble film forming polymers such as pullulan. (Final Rej. 3.) The Examiner also found that Leung described examples of sweeteners and flavoring agents that can be used in the film. (*Id.*) Additionally, the Examiner found that Leung disclosed “a method of making

¹ US Patent No. 7,025,983 B2, issued to Leung et al., Apr. 11, 2006.

a dissolvable film comprising mixing the film-forming ingredients and aqueous mixture to form a polymer gel, adding the oil mixture (substrate) to the gel and drying the mixture to form a film.” (*Id.*) According to the Examiner, the difference between the prior art and the instant claims is that Leung did not teach (a) adding the substance to the film *after* the film is made, and (b) encapsulating the substance. (*Id.* at 3-4.)

However, the Examiner determined that these steps would have been obvious to a person of ordinary skill in the art at the time the invention was made. (*Id.* at 4.) The Examiner reasoned that adding the substance after mixing the film forming ingredients would have been obvious to maintain the integrity of the substance (*id.*), and “allows one of ordinary skill to ensure that the appropriate amount of substance is applied to the film to achieve the desired results of the substance” (*id.* at 4-5).

The Examiner also reasoned that encapsulating a substance was well known in the pharmaceutical industry to delay the release of the substance or protect the substance from an unfavorable condition. According to the Examiner, “[t]his reasoning could lead one of ordinary skill in the art of making dissolvable films to coat the substance.” (*Id.* at 4.) Further, the Examiner found that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to encapsulate a volatile substance to reduce the evaporation of the substance, which would allow the substance to be used at maximum strength for its intended purpose. (*Id.*)

Appellants contend that Leung does not teach a “step of adding a substance after the film is made, or provide any motivation to do so.” (App. Br. 5.) Instead, “Leung teaches ... mixing all its ingredients together and then forming a film.” (*Id.*) Additionally, Appellants contend that Leung

does not provide motivation to encapsulate substances because Leung “makes absolutely no reference to the use of encapsulated substances,” and instead teaches a preferred method of preparing films containing volatile substances without heating to avoid “undesirable losses of volatile ingredients to evaporation” (*Id.*) (citing Leung 11:62-12:1.) Appellants also assert that Leung theorizes “that the pullulan used in making its films ‘entraps’ the volatile oils in the oral cavity to provide extended efficacy.” (*Id.* at 6) (citing Leung 3:6-9; 4:15-19.) Therefore, according to Appellants, the Examiner’s rejection lacks evidentiary support and relies upon impermissible hindsight. (*Id.* at 6-7; Reply Br. 3.)

The issue is whether Appellants established that the Examiner erred in determining that (a) adding volatiles and/or active substances after forming Leung’s film, and (b) encapsulating the Leung’s added substance, were suggested although Leung does not describe either step and no additional evidentiary support is provided.

Findings of Fact

1. Leung describes a dissolvable film comprising a water soluble film-forming polymer such as pullulan and at least one oral care agent, such as antimicrobial agents and salivary stimulants, e.g., essential oils, or a pharmaceutically active agent. (Leung Abstract and 2:67-3:1; 3:10-12.)

2. Leung describes that “[t]he film former used to make the films ... entraps the oral care agents in the oral cavity to provide extended efficacy.” (*Id.* at 3:6-9.)

3. Leung describes preparing the film of the invention in the following manner:

[M]ixing a film forming agent and at least one stabilizing agent to provide a film-forming mixture; dissolving water-soluble ingredients in water to provide an aqueous solution; combining the film-forming mixture and the aqueous solution to provide a hydrated polymer gel; mixing oils to form an oil mixture; adding the oil mixture to the hydrated polymer gel and mixing to provide a uniform emulsified gel; casting the uniform gel on a substrate; and drying the cast gel to provide a film.

(*Id.* at 3:16-24.)

4. Leung teaches a preferred method for making a film containing essential oil that hydrates the film-forming ingredients without heating the water, explaining that “heating results in undesirable losses of volatile ingredients to evaporation, which also affects the germ killing activity of the composition due to the loss of essential oils.” (*Id.* at 11:62-12:1.)

5. Leung does not describe forming the film prior to applying a substance to the film.

6. Leung does not describe encapsulating the substance applied to the film.

Principles of Law

The Examiner bears the initial burden of establishing a prima facie case of obviousness. *See In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). A prima facie case of obviousness is made by presenting evidence that the “reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed substitution, combination or other modification.” *In re Lintner*, 458 F.2d 1013, 1016 (CCPA 1972).

Analysis

Appellants and the Examiner agree that Leung did not describe forming a dissolvable film by first forming the film and then applying a substance to the film, or by using an encapsulated substance, as claimed. Nor has the Examiner found that Leung provided any suggestion to modify its method to incorporate these steps. Rather, the Examiner relied upon the ordinary skill in the art at the time of the invention to reject the claims as obvious. However, the Examiner failed to provide any evidentiary support of the specific understanding or principle within the knowledge of the skilled artisan that would have motivated the modification apart from knowledge gained by Appellants' invention. *See Lintner*, 458 F.2d at 1016.

Specifically, the Examiner's analysis is missing evidence that a skilled artisan at the time of the invention would have known that (a) adding a substance to a film after the film was formed would have maintained the integrity of the applied substance and/or ensured that an effective amount of substance was applied to the film, and (b) an encapsulated substance could be beneficially added to a dissolvable film. Rather, the Examiner merely postulated as to why one of ordinary skill in the art at the time of the invention would have found each of these modifications obvious, apart from the teachings of Leung. Such a conclusion, without more, is insufficient to establish a prima facie case of obviousness. *See Lintner*, 458 F.2d at 1016; *see also In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

CONCLUSION OF LAW

Appellants have shown error in the rejection. The Examiner did not provide evidence that it would have been obvious to a person of ordinary

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skill in the art at the time of the invention who reviewed Leung to prepare a dissolvable film by (a) adding volatiles and/or active substances after forming the film, and (b) encapsulating the added substance.

SUMMARY

We reverse the rejection of claims 1-13 under 35 U.S.C. § 103(a) as obvious over Leung.

REVERSED

cdc

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